IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

LISA FERRELL, as Special Administrator of The Estate of Jordan Dixon, deceased,	)	
Plaintiff,	)	
v.	)	CIVIL NO. 16-CV-00192-DRH-RJD
UNITED STATES OF AMERICA,	)	
Defendant.	)	

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant, United States of America, by its attorneys, Donald S. Boyce, United States Attorney for the Southern District of Illinois, and Suzanne M. Garrison, Assistant United States Attorney, moves for summary judgment pursuant to Fed.R.Civ.P. 56, stating as follows:

Introduction

On June 2, 2014, Dr. Quaas, a pediatrician employed by the Southern Illinois Healthcare Foundation[1], a federally qualified health center, prescribed minocycline, an antibiotic, to 15-year-old Jordan Dixon as treatment for acne. On July 3, 2014, Jordan presented to Dr. Quaas with a fever, rash, and oral lesions, and Dr. Quass immediately referred him to the Cardinal Glennon Children's Hospital's Emergency Department, where he was seen later that morning, based on a

1 SIHF is an entity deemed as a Public Health Service employee under the Federally Supported Health Centers Assistance Act ("FSHCAA"), 42 U.S.C. § 233(g)-(n), and by operation of the FSHCAA, SIHF and its employees, who are acting within the scope of their employment, are eligible for coverage under the FTCA, 28 U.S.C. §§ 1346(b), 2041(b), 2671-80. Therefore, this Court has exclusive jurisdiction over this action, pursuant to 28 U.S.C. § 1346(b)(1), because Plaintiff seeks money damages against the United States for personal injury alleged to be caused by Government employees while acting within the scope of their employment. Venue is proper, pursuant to 28 U.S.C. § 1391(b), because the United States, by and through its agents, resides within the Southern District of Illinois, and the alleged acts giving rise to this claim occurred within the Southern District of Illinois.

concern that Jordan had measles. On December 21, 2014, Jordan died after four hospitalizations at Cardinal Glennon[2]. The death certificate lists the cause of death as myocarditis; DRESS syndrome, RSV; and Rhinovirus, Enterovirus.[3] "DRESS" refers to Drug Reaction with Eosinophilia and Systemic Symptoms, a rare, serious adverse drug reaction involving a complex immune system response.

The instant Federal Tort Claims Act (FTCA) action pleads wrongful death and survival claims and alleges that Dr. Quaas prescribed minocycline to Jordan and: 1) negligently and carelessly failed to recognize the signs and symptoms of an adverse drug reaction or DRESS syndrome; 2) negligently and carelessly failed to diagnose an adverse drug reaction or DRESS syndrome; 3) negligently and carelessly failed to attribute the signs and symptoms of an adverse drug reaction or DRESS syndrome to minocycline; 4) negligently and carelessly failed to recommend the immediate discontinuation of minocycline; and 5) negligently and carelessly failed to appropriately treat Jordan Dixon's adverse drug reaction. The administrator of Jordan's estate, Jordan's mother, Lisa Ferrell, seeks $10 million.

Plaintiff has disclosed one purported expert witness, Dr. Roy Colven. The United States has filed a motion to exclude his testimony under *Daubert.*[4] Dr. Colven has testified that DRESS is a relatively rare condition that has not been adequately studied and there is no consensus

---

[2] Cardinal Glennon is not a defendant in this case. Plaintiff named Cardinal Glennon in a malpractice action presently pending in St. Clair County, but has voluntarily dismissed it from the lawsuit.

[3] Included as Attachment 1.

[4] If Dr. Colven's testimony is excluded, there is no basis for concluding that any of the alleged conduct of the United States was a proximate cause of the decedent's death and summary judgment would be proper. *Alexander v. Mt. Sinai Hosp. Medical Center*, 484 F.3d 889, 903 (7th Cir. 2007) (Plaintiff had "to present expert testimony to establish the standard of care and that its breach was the cause of the plaintiff's injury.").

on its appropriate treatment, though it should involve discontinuing the offending drug. (Att. 5 at p. 46, 81). Based on his testimony, Dr. Colven cannot determine when the decedent took the minocycline or how many pills he consumed. Even if decedent discontinued the drug, the nature of DRESS syndrome is that once the immune system reaction occurs, a course is set in motion which might be irreversible. Plaintiff cannot establish causation in this case and summary judgment should enter in favor of the United States.

Supporting Documentation

In support of this motion, the United States submits the following:

Att. 1: Death Certificate

Att. 2: "Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)," UpToDate Article, Jean-Claude Roujeau

Att. 3: CV of Plaintiff's Expert, Dr. Colven

Att. 4: Report of Dr. Colven

Att. 5: Deposition of Dr. Colven, Cited Portions Only

Att. 6: Deposition Exhibit 1, July 11 Cardinal Glennon Record

Att. 7: Excerpts from Plaintiff Lisa Ferrell's Deposition

Att. 8: "Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): An Original Multisystem Adverse Drug Reaction. Results from the Prospective RegiSCAR Study, British Journal of Dermatology (2013) 169, pp. 1071-1080, Sylvia H. Kardaun, Jean-Clean Roujeau et al., with "Appendix S1—DRESS validation score." The article is cited as footnote 13 in the UpToDate Article attached hereto as Att. 2..

Att. 9: CV of Dr. Megan Cooper, Defendant's Expert

Att. 10: Report of Dr. Cooper

DRESS Syndrome

DRESS is a rare, potentially life threatening, drug-induced hypersensitivity reaction that includes skin eruption, hematologic abnormalities (eosinophilia[5], atypical lymphocytosis[6]), lymphadenopathy, and internal organ involvement (liver, kidney, lung).[7] DRESS is characterized by a two to eight week latency between drug exposure and disease onset, a prolonged course with frequent relapses despite the discontinuation of the culprit drug, and frequent association with the reactivation of a latent human herpesvirus infection. (Att. 2, Introduction, p. 1). "DRESS represents a challenging diagnosis, reached after exclusion of other diseases. Diagnosis can be delayed or go unrecognized as drug related because of the variable presentation, course, severity, relatively later onset, gradual evolution and long duration, even after stopping the drug, or because of clinical similarity to infectious collagen vascular or lymphoproliferative diseases." (Att. 8, p 1072). To help clinicians in confirming or excluding the diagnosis of DRESS, the European Registry of Severe Cutaneous Adverse Reactions (RegiSCAR) devised a scoring system based upon clinical features, extent of skin involvement, organ involvement, and clinical course. (Att. 2, Diagnosis, p. 7). The RegiSCAR scoring system is attached hereto as an appendix to the Kardaun article included as Attachment 8).

---

[5] Eosinophilia is an abnormal increase in the number of eosinophils in the blood that is characteristic of allergic states and various parasitic infections. *Webster's Medical Desk Dictionary* (1986).

[6] An increase in the number of lymphocytes in the blood, usually associated with chronic infections or inflammations. *Webster's Medical Disk Dictionary* (1986).

[7] Jean-Claude Roujeau, "Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)," Introduction, UpToDate, https:/www.uptodate.com/contents/drug-reaction-with-eosinophilia-and-systemic-symptoms-dress (subscription based) (2016). Experts for both parties have cited the Roujeau UpToDate article as a reliable and useful reference. A copy is included as Attachment 2. Citations to the article will identify the pertinent section of the article where the referenced information appears and the page number.

The incidence of DRESS is unknown, though it has been estimated to affect less than 1 out of 100,000 individuals. (Att. 2, Epidemiology, p. 2). The pathogenesis of DRESS is not fully understood, and there are two hypotheses, neither of which can be proven: 1) DRESS is primarily a drug-specific immune reaction acting as a trigger of viral reactivation by as yet unknown mechanisms; 2) the initial event in DRESS is a viral reactivation that induces the expansion of a T cell population cross-reacting with the drug. Tissue damage results. (Att. 2, Pathogenesis, p. 3).

Fever, malaise, lymphadenopathy, and skin eruption are the most common initial symptoms, but they are not always present. (Att. 2, Clinical Presentation, p. 3). Involvement of at least one internal organ occurs in approximately 90 percent of patients; in 50 to 60 percent of patients, two or more organs are involved, most frequently liver, kidneys, and lungs. (Att. 2, Organ Involvement, p. 4). Differential diagnoses should include viral and bacterial infections, which can also be associated with skin eruption, fever, and systemic symptoms. (Att. 2, Differential Diagnoses, p. 7). Systemic corticosteroids are suggested for patients with severe organ involvement, though there have been no randomized trials studying the treatment method, nor is the optimal dose and duration of corticosteroid therapy known. (Att. 2, Patients with Severe Organ Involvement, p. 8). Patients who recover from DRESS may have an increased risk of reaction to structurally unrelated drugs. (Att. 2, Prognosis, p. 9). The mortality rate for DRESS is thought to be 5 to 10%. (*Id.*).

Timeline of Decedent's Care as Summarized by Dr. Colven in his Report and Deposition

Based upon a review of medical records, Dr. Colven summarized the basic timeline of the decedent's illness and treatment in his report and during his deposition. The decedent received a prescription for minocycline from Dr. Quaas, on June 2nd, 2014. (Att. 4, p. 1-2). It is unknown when the decedent took the very first pill, though 60 were prescribed. (Att. 5, p. 21). Dr. Colven

was not able to glean from the materials he reviewed during what period of time the decedent took the 21 pills that were missing from the bottle of 60. (Att. 5, p. 22). He also did not conclude how many of the 21 missing pills decedent may have taken. (Att. 5, p. 21).

On July 1, 2014, the decedent presented with a three-day illness to St. Elizabeth's Urgicare Center ("Urgicare"). (Att. 4, p. 1, 3-4). His symptoms included fever, cough, sore throat, vomiting and a diffuse itchy rash, and the Urgicare physician diagnosed him with a viral syndrome. (Att. 4, p. 3, 4). Minocycline was included as a reported medication, but "drug allergy" was not considered in the differential diagnosis. (Att. 4, p. 1). The Urgicare physician prescribed azithromycin, which the decedent began taking. (*Id.*, Att. 5 at 31). Dr. Colven speculates in his report that, "Presumably, Jordan continues taking minocycline" after this July 1st visit. (*Id.*).

On July 3, 2014, the decedent visited Dr. Quaas and presented with fever, rash and oral lesions, and Dr. Quaas became concerned that the decedent had measles. (Att. 4, p. 1, 4). Dr. Quaas referred the decedent to Cardinal Glennon Children's Hospital's Emergency Department. (Att. 4, p. 1, 4). When seen at Cardinal Glennon later on July 3, 2014, the decedent's mother did not mention minocycline. (Att. 4, p. 1, 4). She did mention that the decedent was taking griseofulvin for a scalp infection. (Att. 4, p. 4). A possible drug allergy to azithromycin was suspected, and Cardinal Glennon instructed the patient to stop taking the azithromycin. *(*Att. 4, p. 1, 4). Tests for measles and mononucleosis were negative. (Att. 4, p. 1, 4). Dr. Colven assumes that, "Because there is no record of anyone telling Jordan or his mother to stop the minocycline, after two medical encounters on July 3, he presumably continues it." (*Id.*).

At the time of the July 3, 2014, Cardinal Glennon ER visit, the decedent had signs of liver inflammation and abnormal kidney function. (Att. 4, p. 4). Lab tests ruled out strep, mononucleosis, and the measles. (Att. 4, p. 4). Cardinal Glennon sent the decedent home with

a diagnosis of a drug reaction due to azithromycin with possible mononucleosis. (Att. 4., p. 4; (Att. 5, 59-60).

The decedent returned to Dr. Quaas's office on July 8, 2014, presenting with a rash, low grade fever, pharyngitis, liver and spleen enlargement, facial swelling, and joint pain and swelling. (Att. 4 at p. 1-2, 5). Dr. Quaas suspected Epstein Barr Virus (EBV), ordered more testing, prescribed prednisone, and referred the decedent to Cardinal Glennon, which admitted him on July 11, 2014. (Att. 4, p. 5; Att. 5 p. 44).

On or about the time of the July 11, 2014 Cardinal Glennon hospitalization, physicians there opined that the deceased had DRESS syndrome due to minocycline use. (*Id.* at p. 2). The presence of eosinophilia on July 11 was helpful in diagnosing a medication reaction because high eosinophilia counts are not expected to result from a viral infection. (Att. 5, at 43). The diagnosis of DRESS included a "history of taking minocycline for the previous month and a half." (Att. 4, p. 5). On July 11, the decedent's mother told Cardinal Glennon that the deceased stopped taking minocycline when the rash started. (Att. 6). After four hospitalizations, the decedent died on December 21, 2014 at Cardinal Glennon Children's Hospital. (Att. 1).

Dr. Colven's Opinions on the Standard of Care

In his deposition, Dr. Colven thought it was within the standard of care that Dr. Quaas attempted to treat the decedent's acne, and that he started with topical medication. (Att. 5, p. 13-14). He found it within the standard of care that Dr. Quaas then prescribed minocycline and further opined that the dosage was appropriate. (Att. 5, p. 15-16, 20). Minocycline is not a new medication, has been available for at least 30 years, and is commonly prescribed for acne. (Att. 5, p. 16). Dr. Colven indicated that both complicated and uncomplicated adverse reactions to minocycline are uncommon, and he continues to prescribe minocycline in his practice. (Att. 5,

p. 17-18). Dr. Colven believed there have been only 20 or even fewer cases of DRESS associated with minocycline. (Att. 5, p. 51). At the time Dr. Quaas prescribed the minocycline, there was no way to determine whether or not the decedent would have an adverse reaction to it, and there was no way to test the decedent for susceptibility to the drug. (Att. 5, p. 18-20). The decedent had no prior known drug allergies or history of adverse drug reactions. (Att. 5, p. 19).

When the decedent first presented to the Urgicare on July 1, 2014, it is possible that he had a virus that preceded the drug reaction. (Att. 5, p. 31). If the decedent had a viral activation, it is not known what effect the minocycline would have had on it if the decedent was taking minocycline intermittently rather than as prescribed. (Att. 5 p. 61-62).

At the time he wrote his report and at the time of his deposition, Dr. Colven had not been advised that Lisa Ferrell testified in her deposition that Jordan had taken no more than 21 minocycline pills. (Att. 5, p. 21-22; Att. 7). Yet, he conceded that the most important thing to take into consideration in determining whether a rash is medication related is the timeline of the dosage to the onset of symptoms. (Att. 5, p. 22-23). It is unknown when Jordan took minocycline prior to development of his symptoms. (Att. 5, p. 23). The process of DRESS is not well-understood in the medical profession. (Att. 5, p. 35). It is possible that the symptoms of DRESS will continue even after the causative drug is stopped. (Att. 5, p. 35, 59-60).

Dr. Colven has opined that Dr. Quaas acted within the standard of care in referring the decedent to Cardinal Glennon on July 3rd. (Att. 5, p. 33). Had his mother taken the decedent to the doctor sooner, rather than wait three to four days before taking him to Urgicare, it might have made a difference in outcome. (Att. 5, p. 37).

As for the July 3rd Cardinal Glennon visit, Dr. Colven states that that a Complete Blood Count (CBC) should have been done. (Att. 5, p. 38-39). The blood tests that were taken showed

signs of liver and kidney involvement. (Att. 5, p. 39). Dr. Colven states that he might well have admitted Jordan to the hospital for further evaluation of the abnormal liver and kidney tests. (Att. 5, p. 40, 41). By July 3rd, due to the liver and kidney dysfunction there was already an increased risk of death. (Att. 5, p. 41-42). It is not known at what point in time before July 3rd that the decedent was already showing signs of organ involvement. (Att. 5, p. 81). While the presence of eosinophilia on July 11th aided in the diagnosis of a drug reaction (as opposed to a viral infection) it is unknown whether additional tests (if conducted) would have shown eosinophilia (which are not associated with viral infections) on July 3rd. (Att. 5, p. 44).

Dr. Colven testified that there is no consensus of the appropriate treatment of DRESS. (Att. 5, p. 46). The use of systemic steroids (like the prednisone which Dr. Quaas prescribed on July 8th) to treat DRESS is commonplace, though tapering of steroids can lead to rebounds. (Att. 5 at 46-47). The use of prednisone and whether or not it has a true impact is somewhat controversial in the literature. (Att. 5, p. 78). Dr. Colven stated that it is "really an unknown question whether or not early administration [of prednisone] is going to necessarily lead to prevention of death for certain." (Att. 5, p. 79). There was evidence on July 3rd of organ involvement and for that reason we do not know "if the cow had left the barn on July 3rd" and that there was nothing humanly possible that could have been done to save the patient. (Att. 5, p. 60-61, 79). In a nutshell, Dr. Colven testified, "We just don't know whether or not prednisone would have made a big difference in the long-term prognosis at an earlier point." (Att. 5, p. 70). Compliance with discharge instructions also could have affected the outcome in Jordan's case. (Att. 5, p. 51-52).

Dr. Colven believes that Dr. Quaas was within the standard of care on July 8th when he recognized that the decedent still suffered from hyper-inflammation and prescribed prednisone,

directly contradicting an allegation in the Complaint that Dr. Quaas failed to properly treat the DRESS syndrome. (Att. 5, p. 45, 64). Dr. Colven also believed that Dr. Quaas acted within the standard of care in referring the decedent to Cardinal Glennon a second time on July 10th. (Att. 5, p. 46).

Prior to July 3rd there were four other drugs taken by Jordan that have an association with DRESS syndrome-- Tylenol, ibuprofen, azithromycin, and griseofulvin. (Att. 5, p. 31, 64). During his hospitalizations, Cardinal Glennon prescribed the decedent numerous drugs, some of which are associated with DRESS, and it cannot be known whether he developed a new, subtle undiagnosed case of DRESS as a result of a new medication. (Att. 5, p. 48, 63). It is possible, though rare, that the patient even could have developed an allergy to steroids. (Att. 5, p. 48). Despite a lack of factual underpinnings, Dr. Colven opined that it was "in the probable category" that minocycline caused the decedent's DRESS. (Att. 5, p. 58). In a line of questioning directed to the differential diagnoses that Cardinal Glennon should have considered on July 3rd, Dr. Colven testified as follows: "So did we overturn every single rock of diseases that this possibly could be? No. Did we overturn the ones that are the most likely? Well, yes and no. I mean, we. . . we. . . I think it could have been. . . there could have been a better job done of that, at least with respect to the medication allergy differential, and I don't think it's. . . certainly a good job was done looking for infections multiple times, but in my mind I'd still put it in the probable category." (Att. 5 p. 58).

Dr. Colven indicated that "There is a better chance that Jordan would have been alive had [DRESS] been recognized earlier." (Att. 5, p. 72). However, Dr. Colven also indicated that it is unknown why some patients die from DRESS and why others don't, but organ involvement is what typically leads to death. (Att. 5, p. 30). There might be a genetic or

hereditary component to DRESS as well. (Att. 5, p. 31). A heart biopsy was not taken, but if one had been taken the presence of eosinophil would have helped eliminate potential causes of myocarditis other than DRESS syndrome. (Att. 5, p. 50).

Dr. Colven's report opines that the deceased took minocycline between July 3 and July 11, and that the delay in minocycline cessation allowed the immune reaction to continue in multiple organ systems, more likely than not added to the morbidity associated with DRESS. (Att. 4, p. 5). The assertion in the report that the deceased took minocycline between July 3 and July 11 is based on conjecture and speculation. During his deposition, Dr. Colven conceded that it is unknown when the decedent took his last minocycline pill. (Att. 5, p. 42).

In any event, Dr. Colven concedes that, "It is **unknown** whether earlier cessation of minocycline would have spared Jordan Dixon's later demise due to organ failure related to his exposure to this drug." (Att. 4, p. 5, *emphasis supplied*). Dr. Colven testified that even if the offending drug is stopped, DRESS can worsen on its own. (Att. 5 at 59-60).

While he would not expect Dr. Quaas to recognize DRESS syndrome in particular, Dr. Colven has opined that he should nevertheless recognize an adverse drug reaction. (Att. 5 at 75).

Plaintiff's Burden

The FTCA makes the United States liable in tort claims in the same manner and to the same extent as a private individual in like circumstances. 28 U.S.C. § 2674. An FTCA case is governed by the law of the place where the act or omission occurred. 28 U.S.C. § 1346. This case is controlled by the law of the State of Illinois, where Dr. Quaas, a Belleville practitioner, treated the decedent. *Campbell v. United States*, 904 F.2d 1188, 1192 (7th Cir.1990).

To succeed on a medical malpractice claim under Illinois law, plaintiff must prove: 1) the proper standard of care by which a physician's conduct may be measured, 2) a negligent failure to

comply with the applicable standard and 3) a resulting injury proximately caused by the physician's lack of skill or care. *Walsch v. Chez*, 583 F.3d 990, 995 (7th Cir. 2009). The determination of whether a doctor acted in compliance with the applicable standard of care is limited, by definition, to the circumstances with which he was confronted at the time the medical service was rendered. *Steele v. Provena Hosp.*, 996 N.E.2d 711, 722, 374 Ill.Dec. 1016, 2027 (3d Dist. 2013). The standard of care is not the highest degree of skill that one learned in the profession may acquire; rather, it reflects "reasonable skill such as physicians in good practice ordinarily use and would bring to a similar case in that locality." *Taber v. Riordan*, 83 Ill.App.3d 900, 904, 38 Ill.Dec. 745, 403 N.E.2d 1349 (2d Dist.1980); *Kasongo v. United States*, 523 F.Supp.2d 759, 792 (N.D.Ill.2007).

Because medicine "is not an exact science," but instead "involves the exercise of individual judgment within the framework of established procedures," a diagnosis that results in a difference of opinion nevertheless can be consistent with the exercise of due care. *Id.*, citing *Walski v. Tiesenga*, 72 Ill.2d 249, 261, 21 Ill.Dec. 201, 381 N.E.2d 279 (1978); see also *Campbell* 904 F.2d at 1192.

Illinois courts have consistently held that proximate cause is not established where the causal connection is "contingent, speculative or merely possible." *Newell v. Corres*, 125 Ill.App.3d 1087, 303 N.E.2d 146, 152 (1973); *Manion v. Brant Oil Co.*, 85 Ill.App.2d 129, 229 N.E.2d 171, 175 (1967). In order to recover, "the injury suffered by plaintiff must be the natural and not merely a remote consequence of the defendant's act." *Town of Thornton v. Winterhoff*, 406 Ill. 113, 92 N.E.2d 163 (1950). To establish proximate cause in a medical malpractice case, "a plaintiff must satisfy two requirements: cause-in-fact and legal cause." *LaSalle Bank, N.A. v. C/HCA Dev. Corp.*, 384 Ill.App.3d 806, 828, 893 N.E.2d 949, 970, 323 Ill.Dec. 475, 496 (1st

Dist.2008). "[T]o prove cause-in-fact, a plaintiff must show, within a reasonable degree of medical certainty, that defendants' breach of the standard of care was more probably than not a proximate cause of the resulting injury." *Id.*

Cause-in-fact may be established through a "lost chance" or "loss of chance" theory whereby the defendant's negligent conduct "deprived the plaintiff of a chance to survive or recover from a health problem, or where the malpractice has lessened the effectiveness of the treatment or increased the risk of an unfavorable outcome to the plaintiff." *Holton v. Mem'l Hosp.*, 176 Ill.2d 95, 223 Ill.Dec. 429, 679 N.E.2d 1202, 1209 (1997); *Scardina v. Nam*, 333 Ill.App.3d 260, 266 Ill.Dec. 454, 775 N.E.2d 16, 24 (1st Dist. 2002) (noting that the loss of chance "doctrine is not a separate theory of recovery but, rather, a concept that factors into the proximate cause analysis"); *Lambie v. Schneide*r, 305 Ill.App.3d 421, 239 Ill.Dec. 72, 713 N.E.2d 603, 609 (4th Dist.1999) ("While the 'lost chance' doctrine eliminates a problem of demonstrating 'cause-in-fact,' it does not eliminate the requirement that the plaintiff prove defendant's conduct was the legal cause of his injury.") (citing *Holton*, 223 Ill.Dec. 429, 679 N.E.2d at 1213), cited in *Ford-Sholebo v. United States*, 980 F. Supp. 2d 917, 992 (N.D. Ill. 2013).

"[T]o prove legal cause, a plaintiff must also show that 'an injury was foreseeable as the type of harm that a reasonable person would expect to see as a likely result of his or her conduct.'" *Id.* (quoting *Bergman v. Kelsey*, 375 Ill.App.3d 612, 625, 313 Ill.Dec. 862, 873 N.E.2d 486 (1st Dist.2007)), cited in *Nolan v. United States*, No. 12 C 0247, 2015 WL 5159888, at *7 (N.D. Ill. Sept. 1, 2015). It is insufficient to show merely that an injury occurred; evidence of a bad result does not constitute evidence of lack of skill or negligence. *Crawford v. Anagnostopoulos*, 69 Ill.App.3d 954, 26 Ill.Dec. 234, 387 N.E.2d 1064 (1979). The mere existence of a temporal

relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship. *Ervin v. Johnson &* Johnson, 492 F.3d 901, 904–05 (7th Cir. 2007).

A court is not bound by the mere assertions of an expert, but it must pay special attention to expert testimony, *United States v. Lundy*, 809 F.2d 392, 395 (7th Cir. 1987). Proximate cause is not established where the causal connection between the allegedly negligent act or omission and the injury is contingent or speculative or if the injury would have occurred even in the absence of that act of omission. *Campbell v. United States*, 904 F.3d 1188, 1193–94 (7th Cir.1990). Rather, Plaintiff must show by a preponderance of the evidence that Defendant's failure to comply with the applicable standard of care caused or contributed to the injury giving rise to Plaintiff's cause of action. *Wise v. St. Mary's Hosp.*, 64 Ill.App.3d 587, 589, 21 Ill.Dec. 482, 381 N.E.2d 809 (1st Dist.1978); see also *Kasongo*, 523 F.Supp.2d at 802 (defining causation inquiry as whether "the defendant's breach of the applicable standard of care more probably than not caused [the plaintiff's] injury").

The rule in *Holton* does not absolve a plaintiff in a medical malpractice case from satisfying the requirement that proximate cause must be established by expert testimony to a reasonable degree of medical certainty; the causal connection must not be contingent, speculative, or merely possible. *Townsend v. University of Chicago Hospital*., 318 Ill.App.3d 406, 413, 251 Ill.Dec. 877, 741 N.E.2d 1055 (2000).

Summary Judgment Standard

Summary judgment is appropriate when the pleadings and the evidence before the court demonstrate that there exists no genuine issue with regard to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). If the record, taken as a whole, could lead no rational trier of fact to a judgment in favor of the nonmoving party, then summary

judgment is warranted. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586 (1986). The initial burden rests with the moving party to direct the court to the portions of the record which indicate that there is no dispute as to a material fact. *Celotex Corp.v. Catrett*, 106 S.Ct. 2458, 2553 (1986).What constitutes a "material" fact is determined by the elements of the claim. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986).

Once the movant satisfies its burden, to survive a motion for summary judgment the nonmovant must rebut such a showing by coming forward with sufficient evidence on which a jury could reasonably find in its favor. *Celotex*, 477 U.S. at 324. While all evidence must be viewed in the light most favorable to the non-moving party, to satisfy its burden, the plaintiff must present more than a "mere . . . scintilla of evidence." *Anderson*, 477 U.S. at 252. Additionally, if the plaintiff cannot make a sufficient showing to establish the existence of an essential element for which the plaintiff bears the burden at trial, summary judgment is appropriate. *Celotex*, 477 U.S. at 322.

Proof of Causation is Lacking in this Case

Dr. Colven opines that because Dr. Quaas failed to tell the decedent to stop taking minocycline after the July 3, 2014 visit, the decedent must have continued taking the pills for an eight day period of time from July 3rd to July 11th. That is rank speculation. Dr. Colven has conceded that it is unknown when the decedent took the last minocycline pill. (Att. 5, p. 21-22). Lisa Ferrell has testified that she doesn't know when the decedent took the last pill. (Att. 7). The entire lynchpin of Dr. Colven's opinion is that a delay in discontinuing minocycline from July 3 to July 11th contributed to added morbidity. (Att. 4, p. 6). DRESS is associated with a gradual evolution, its signs and symptoms evolve sequentially, and it is only diagnosed after other diseases are excluded. (Att. 8, p. 1072, 1079). "The first symptoms may be seemingly harmless and

each feature may be of variable onset and severity, leading to confusion and delay in diagnosis." (Att. 8, p. 1076).

As for the practical effect of failing to tell the patient to stop taking the pills, Dr. Colven's testimony is full of conjecture He testified as follows: "Would it have been helpful to certainly tell Jordan and his mother that this was possibly due to exposures to something he may be continuing to take? That would have been helpful at least to eliminate the possibility of further exposure to a cause that hadn't yet been identified." (Att. 5, p. 21). The possible failure to limit exposure to minocycline is a far cry from establishing proximate cause of death due to minocycline. Dr. Colven has opined that, if Dr. Quaas did not tell the decedent to stop taking the pills, but the decent had stopped taking the pills, the failure to tell him to stop taking the pills was not a causative factor in the death. (Att. 5, p. 82). And the nature of DRESS syndrome is such that the immune system reaction can continue, even if the offending drug is stopped. Recall that Dr. Colven did feel that Dr. Quaas was within the standard of care in prescribing minocycline in the first instance. According to Dr. Colven, it is not known whether the decedent's DRESS syndrome had progressed so far by his first visit to Dr. Quaas on July 3, 2004, that the course of the disease was irreversible. (Att. 5, p. 60-61, 79).

Experts' work is admissible only to the extent it is reasoned, uses the methods of the discipline, and is founded on data." *Lang v. Kohl's Food Stores, Inc.*, 217 F.3d 919, 924 (7th Cir.2000). Here, we have a witness whose opinion is not founded on data. He is merely speculating that the decedent continued to take minocycline from July 3 to July 11. As for the assertion that Dr. Quaas' failure to tell the decedent to stop taking the minocycline led to an increased risk of death, causation cannot be established if we don't know when the decedent stopped taking the pills. We definitively know that he did not take them twice per day as

prescribed, and that he consumed no more than 21 pills. By July 3rd, because there were already signs of organ involvement, Dr. Colven cannot say whether earlier administration of prednisone would have prevented death. (Att. 5, p. 60-61, 79).

Finally, Dr. Colven speculates that the outcome of this case might have been better if DRESS had been diagnosed sooner. An examination of the RegisSCAR criteria reveals that DRESS could not have been diagnosed any sooner. It is diagnosed only after lab testing enables clinicians to exclude other diseases, including viral infections. By twice referring the decedent to Cardinal Glennon, Dr. Quaas acted within the standard of care, ensuring that lab testing would be done to determine what was causing the decedent's viral symptoms.

Dr. Colven has testified that DRESS is a relatively rare condition that has not been adequately studied, and there is no consensus on the appropriate treatment for it. (Att. 5 at p. 81). The pathogenesis of the disease is not well-understood. (Att. 2, Pathogenesis, p. 3). The course of DRESS syndrome can continue even if the offending drug is discontinued. (Att. 2, Introduction, p. 1). The very nature of DRESS syndrome makes it ill-suited to serve as the subject of a malpractice action due to difficulties in establishing causation where medical knowledge is lacking.

"The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur. Based on such predicate knowledge, it may then be possible to fasten legal liability for a person's disease or injury." *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999)(Physician's testimony that customer's fall in store caused hormonal damage leading to fibromyalgia was not sufficiently reliable in part because neither expert nor medical science knew exact process that resulted in fibromyalgia or factors that

triggered process), *see also*, *Vargas v. Lee,* 317 F.3d 498 (5th Cir.2003)(Scientific understanding of fibromyalgia had not progressed sufficiently since *Black* to permit the admission of the expert's testimony).

A detailed examination of a Louisiana case involving Stevens-Johnson syndrome elucidates Plaintiff's inability to establish causation. Like DRESS, Stevens-Johnson syndrome is a severe adverse cutaneous drug reaction. In *Jordan v. Ryan*, 684 So.2d 1030 (La.App. 4 Cir. 1996), the plaintiff filed a malpractice action against her gynecologist for his failure to recognize that she developed Stevens Johnson syndrome after he prescribed Septra for urinary tract and yeast infections. Evidence at trial revealed that the plaintiff obtained the Septra prescription from Dr. Ryan on December 4th. On December 5th, she called Dr. Ryan and complained of increased genital itching and burning; he told her to keep taking the Septra and to call back on December 7th if she continued to have problems. When plaintiff next saw Dr. Ryan on December 9th she was complaining of blurred vision, increased genital itching and burning, trouble keeping lipstick on her lips, and a sore throat. Dr. Ryan instructed her to stop taking the Septra and, due to ulcerations on her labia, reached a differential diagnosis of herpes. Though she had disconintued the Septra, by December 11th, plaintiff went to the hospital and was diagnosed with an urticarial rash, even though the examining physician was familiar with Stevens-Johnson syndrome. Though plaintiff prevailed after a four day trial, the case was reversed on appeal due to plaintiff's failure to establish causation.

Plaintiffs theory of negligence was that Dr. Ryan was negligent in delaying to advise the plaintiff to stop taking the medication at the outset of her first symptoms; in failing to see her immediately on December 7th, and in failing to diagnose an allergic reaction.

At trial, the doctors agreed that stopping the drug after its introduction would have no effect on whether the patient developed the syndrome. All the doctors testified about the difficulties encountered in diagnosing the syndrome, which cannot be diagnosed positively until the outbreak of symmetrical blistering in the mouth and on the skin. There was no evidence that plaintiff was having those symptoms even as late as her hospital visit. As to treatment, the expert testimony was that steroids are used, though there is not conclusive evidence that they are helpful. The experts also found it possible that the syndrome had been induced by Amoxicillin or by the herpes virus. One of the experts testified that even if the Septra was the cause of the syndrome, stopping the dosages would not have made any difference in stopping the onset of the syndrome's symptoms and the reaction would have been the same whether or not the dosage was stopped on December 7th or 9th.

On appeal, the reviewing court found the differential diagnosis of herpes was reasonable. As for the failure to diagnose, Dr. Ryan did not breach the standard of care because the syndrome was rare, was not easily diagnosed, and would have occurred even if the Septra dosage was discontinued on the 7th rather than the 9th. In closing, the court noted that, "A physician's conduct in treatment of a patient is evaluated in terms of professional standards and the current state of medical science, and a physician's judgment is evaluated in light of the facts known at the time of the patient's treatment, not on the basis of hindsight of information later learned." *Id.* at 1035-36. *See also, Littlejohn v. State*, 87 A.D.2d 951, 952, 451 N.Y.S.2d 225, 226 (1982)(Affirming finding of no liability for failure to diagnose Stevens Johnson syndrome).

The concurring opinion in *Jordan v. Ryan* also highlighted some aspects of the expert testimony that are common to this case. As to allergic reactions to medication *in general*, it is best to discontinue the medication as soon as possible because, the more one takes of the

medication, the worse the allergic reaction may be. However, the same point does not hold true for Stevens-Johnson syndrome or DRESS. The reactions are not dose related, and the reaction will run its course if the first dose is taken. Additionally, the concurring opinion noted that the defendant's failure to give plaintiff steroids can be the cause of damages only if the steroids would have affected the course of Stevens-Johnson syndrome. The medical testimony was either that steroids have no effect on Stevens-Johnson Syndrome or that it is unknown to medicine as to whether steroids will have any effect. "Although steroids are sometimes used in connection with Stevens-Johnson syndrome, as was eventually done in this case, this apparently is just a matter of doing something as opposed to nothing, and not because of any particular expectation of alleviating the reaction." *Id.* at 1036.

The expert opinion of Dr. Megan Cooper, a Pediatric Rheumatologist retained by the United States, highlights the striking similarities between this case and *Jordan v. Ryan*. In her report, Dr. Cooper opines that "It is not clear from the evidence provided that Jordan's outcome would have been different if DRESS were diagnosed at his initial visit with Dr. Quaas on July 3, 2014 rather than at his July 11, 2014 hospitalization." (Att. 10 at 10). If steroid treatment had started earlier, "This immune suppression would have resulted in a similar risk of complications that this patient experienced and which more than likely played a significant role in his death, including sepsis and endocarditis." (Att. 10 at 10).

Here, not only are we lacking information about when the decedent consumed the minocycline, not enough is known about DRESS syndrome by the medical community to say whether it was too late to save the decedent after July 3rd, or whether DRESS would continue its course even after the offending drug was discontinued, or whether earlier administration of steroids would have improved the chances of survival, particularly after there were signs of organ

involvement on July 3rd. Dr. Colven cannot establish causation through his testimony. His opinions are speculative and are not grounded in fact. If there was a "loss of chance," Dr. Colven has not explained the risk or made any significant effort to explain how or how much the claimed negligence increased the decedent's risk of death or loss chance of recovery. The "loss of chance" theory, is not a license to allow speculation rather than reasoned opinion

An expert opinion is only as valid as the reasons for the opinion. When there is no factual support for an expert's conclusions, the conclusions alone do not create a question of fact. *Gyllin v. College Craft Enterprises, Ltd.*, 260 Ill.App.3d 707, 715, 198 Ill.Dec. 649, 633 N.E.2d 111 (1994), cited in *Aguilera v. Mount Sinai Hosp. Med. Ctr.*, 293 Ill. App. 3d 967, 974, 691 N.E.2d 1, 6 (1997), as modified on denial of reh'g (Jan. 21, 1998). Here, Dr. Colven's report states that, "It is **unknown** whether earlier cessation of minocycline would have spared Jordan Dixon's later demise due to organ failure related to his exposure to this drug." (Att. 4, p. 5, *emphasis supplied*). This concession is fatal to Plaintiff's ability to establish causation in this case.

WHEREFORE, summary judgment should be entered in favor of the United States.

Respectfully submitted,

DONALD S. BOYCE
United States Attorney

s/ Suzanne M. Garrison
SUZANNE M. GARRISON
Assistant United States Attorney
United States Attorney's Office
Nine Executive Drive
Fairview Heights, Illinois 62208-1344
Phone: (618) 628-3700
Fax: (618) 622-3810
Email: suzanne.garrison@usdoj.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

LISA FERRELL, as Special Administrator of The Estate of Jordan Dixon, deceased, Plaintiff, v. UNITED STATES OF AMERICA, Defendant.	)	CIVIL NO. 16-CV-00192- DRH-RJD

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2017, I electronically filed the foregoing

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

with the Clerk of Court using the CM/ECF system to the following registered participants:

Thomas Q. Keefe, III – keefetq@gmail.com; debbie@tqkeefe.com

Respectfully submitted,

DONALD S. BOYCE
United States Attorney

s/ Suzanne M. Garrison
SUZANNE M. GARRISON
Assistant United States Attorney
United States Attorney's Office
Nine Executive Drive
Fairview Heights, Illinois 62208-1344
Phone: (618) 628-3700
Fax: (618) 622-3810
Email: suzanne.garrison@usdoj.gov